SEP 2 6 2000

K002360

510(k) Summary

Submitter's Name:	Parts Port, Ltd. 1801 Walthall Creek Drive Colonial Heights, VA 23834
Official Contact:	Cathy Sebastian President, Parts Port, Ltd.
Establishment Registration#:	1125761
Telephone Number:	(804) 530-1233
Fax Number:	(804) 530-1128
Date:	August 1, 2000
Proprietary or Trade Name:	Cloud Cuff™
Common/Usual Name:	Blood Pressure Cuff
Classification Name:	Cuff, Blood Pressure (per CFR 870.1120)
Predicate Device:	Technicuff™ (k942259)

Device Description:

The device is comprised of two tubes attached to an inflatable bladder which is covered with a stitched nylon cover. The device is wrapped around a patient's limb and secured by a hook and loop closure. The tubing connects to a non-invasive blood pressure measurement system. The blood pressure cuffs contain no latex. Sizes will include pediatric through large adult. Each cuff will be packaged in a polyethylene (non-sterile) bag.

Intended Use:

The Cloud Cuff™ blood pressure cuff is used in conjunction with non-invasive blood pressure monitoring systems by personnel properly trained in the use of manual and automatic sphygmomanometers. The device is non-sterile and is intended as a reusable multi-patient device. It is recommended that the cuff exterior and exposed tubing should be wiped with a disinfectant after every use. It is available in pediatric through large adult sizes.

Technology Comparison to Predicate Device:

Item	Cloud Cuff™	Technicuff™
Intended Use	Indirect measurement of blood pressure	Indirect measurement of blood pressure
Intended Population	Pediatric – Adult	Infant – Adult
Labeling	Reusable	Disposable
Cleaning Instructions	Wipe with disinfectant	N/A
Outer Material	Nylon fabric	Nylon fabric
Bladder Material	PVC (non-toxic)	PVC (non-toxic)
Fastener Material	Velcro (hook & loop)	Velcro (hook & loop)
Pressure Limits	0 – 300 mmHg	0 – 300 mmHg
Usable Range	18 – 41 cm	18 – 41 cm
Usable Life	10,000 inflations	1000 inflations
Cuff Inflation & Deflation Characteristics	Linear	Linear
Number of tubes	2	2
Bladder Size	Full (360° Coverage)	Full (360° Coverage)

Summary of Non-Clinical Performance Testing:

Bench testing was conducted to demonstrate performance of the Cloud Cuff™ blood pressure cuff. The key performance requirements and the test methodologies were selected from the ANSI/AAMI SP-9-1994 standard for Nonautomated sphygmomanometers. This standard is referred to in the FDA Guidance for Industry document titled "Non-Automated Sphygmomanometer (Blood Pressure Cuff) Guidance Version 1." The cuff performance testing included but was not limited to Cuff Closure/construction, Pressure Capacity and Repeated Inflation testing, and systems leak testing.

Conclusions:

In accordance with the Federal Food, Drug and Cosmetic Act and 21 CFR Section 807, and based on the information provided in this premarket notification, Parts Port, Ltd. concludes that the Cloud Cuff™ blood pressure cuff is safe, effective and substantially equivalent to the predicate device as described herein and meets the appropriate requirements of ANSI/AAMI SP-9.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 26 2000

Parts Port, Ltd.
c/o Ms. Cathy Sebastian
President
1801 Walthall Creek Drive
Colonial Heights, VA 23834

Re: K002360
Cloud Cuff™
Regulatory Class: II (two)
Product Code: DXQ
Dated: August 2, 2000
Received: August 3, 2000

Dear Ms. Sebastian:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

for James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indication for Use Statement

510(k) Number: K002360

Device Name: Cloud Cuff™

Indications for Use: The Cloud Cuff™ blood pressure cuff is used in conjunction with non-invasive blood pressure monitoring systems by personnel properly trained in the use of manual and automatic sphygmomanometers. The device is non-sterile, intended as a reusable device and is available in pediatric through large adult sizes. The cuff exterior and exposed tubing should be wiped down with a disinfectant after every use.

Division of Cardiovascular & Respiratory Devices
510(k) Number K002360